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APPLICATION NO.		FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/068,533	10/068,533 02/05/2002		Robert H. Dahla	CB-11-1	9992	
21394	7590	05/25/2006		EXAMINER		
		ORPORATION	PEFFLEY, MICHAEL F			
680 VAQUEROS AVENUE SUNNYVALE, CA 94085-3523				ART UNIT	PAPER NUMBER	
	·			3739	3739	
				DATE MAILED: 05/25/2006		

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)					
	10/068,533	DAHLA ET AL.					
Office Action Summary	Examiner	Art Unit					
	Michael Peffley	3739					
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. ED (35 U.S.C. § 133).					
Status							
1) Responsive to communication(s) filed on 12 Ap	<u>oril 2006</u> .						
2a)⊠ This action is FINAL . 2b)☐ This	action is non-final.						
3) Since this application is in condition for allowar							
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.					
Disposition of Claims							
4)⊠ Claim(s) <u>1-52</u> is/are pending in the application.							
4a) Of the above claim(s) 1-11,13-21 and 27-50	4a) Of the above claim(s) 1-11,13-21 and 27-50 is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.	· · · · · · · · · · · · · · · · · · ·						
-	☐ Claim(s) <u>12,22-26,51 and 52</u> is/are rejected.						
7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or	r election requirement						
are subject to restriction under	r ciconon requirement.						
Application Papers							
9) The specification is objected to by the Examine							
10)⊠ The drawing(s) filed on <u>05 February 2002</u> is/are		-					
Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct	- ' '						
11) The oath or declaration is objected to by the Ex							
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign	priority under 35 H S C & 110/a	\-(d\ or (f)					
a) ☐ All b) ☐ Some * c) ☐ None of:	priority under 33 0.3.0. § 113(a)-(d) 01 (1).					
1. ☐ Certified copies of the priority documents	s have been received.						
2. Certified copies of the priority documents	s have been received in Applicati	ion No					
3. Copies of the certified copies of the prior	rity documents have been receive	ed in this National Stage					
application from the International Bureau	, ,,,						
* See the attached detailed Office action for a list	of the certified copies not receive	∍d.					
Attachment(s)							
Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4)						
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) 🔲 Notice of Informal F	Patent Application (PTO-152)					
Paper No(s)/Mail Date	6) Other:						

Applicant's arguments and amendments, received April 12, 2006, have been fully considered by the examiner. The following is a complete response to the April 12, 2006 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the originally filed drawings are deemed to be informal. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

Claims 12, 51 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Abele et al (5,403,311).

Figure 8 of the Abele et al reference discloses a device comprising an elongate probe having active (56) and return (58,60) electrodes at the distal end. The return electrode(s) include a coil having about 3-10 turns. Column 9, lines 9-25 discloses how the helical electrodes are connected to ground so the device acts in a bipolar manner with active electrode (56). The method of using the device inherently includes providing the device in proximity to tissue and delivering energy from the active to the return

electrode to ablate tissue. The Figure clearly shows the active electrode (i.e. needle electrode) has a much smaller surface area than the active electrode.

Claims 12, 23, 51 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al (5,507,743).

Edwards et al disclose an ablation device comprising an elongate probe (22 – Figure 4a) having active and return electrodes (12,14) at the distal end. Column 5, lines 15-16 disclose the return electrode as having 4 or fewer coils, and column 1, lines 58-60 disclose that temperatures of greater than 45 degrees Celcius are used to treat tissue. The step of providing the electrodes to tissue and delivering energy from the active to the return electrode is fully supported in the Edwards et al disclosure. The return electrode having the turns inherently has a larger surface area than the active electrode since it is longer.

Claim Rejections - 35 USC § 103

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abele et al ('311) in view of the teaching of Nardella ('193).

Abele et al fail to disclose the specific power levels and temperature ranges used during the cardiac ablation procedure.

As addressed previously, Nardella disclose another cardiac ablation device and specifically teach of the known voltage and temperature ranges associated with such devices.

Page 4

To have operated the Abele et al device in any well known parameter range for the ablation of cardiac tissue would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Nardella.

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abele et al ('311) in view of the teaching of Stevens-Wright et al (5,715,817).

Abele et al fail to specifically disclose the use of multiple lumens for providing the active and return electrodes to the distal end of the device. Abele et al is simply silent with respect to the cross-section components of the catheter.

Stevens-Wright et al disclose an electrosurgical device, and specifically teach that electrode leads may be provided through individual channels (see Figures 9-13) and connected to electrodes.

To have provided the Abele et al device with multiple lumens for supporting the multiple electrodes/leads provided at the distal end of the device would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Stevens-Wright et al.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abele et al ('311) in view of the teaching of Imran et al ('554).

Abele et al fail to specifically disclose making the catheter probe from a polyurethane extrusion. Again, the examiner maintains that the use of any well-known materials for making probes would be an obvious design consideration.

Art Unit: 3739

Imran et al, as addressed previously, disclose a probe device very much analogous to the Abele et al probe. In particular, Imran et al disclose that the probe is made from a polyurethane extrusion (col. 2, line 64 through col. 3, line 2).

To have fabricated the Abele et al device from any well known flexible polymer, including an extruded polyurethane, would have been an obvious design consideration for one of ordinary skill in the art, particularly since Imran et al teach that it is known to make analogous probes from such a material.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12, 22-26, 51 and 52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-124 of U.S. Patent No. 6,837,888. Although the conflicting claims are not identical, they are not patentably distinct from each other because providing the electrodes as movable electrodes to afford more flexibility in treating tissue is deemed an obvious design consideration for one of ordinary skill in the art.

Claims 12, 22-26, 51 and 52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 10/072,599. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of a spacer to maintain electrical separation of the active and return electrodes is deemed an obvious design consideration for one of ordinary skill in the art.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to the Abele et al ('311) and Edwards ('743) references have been fully considered but they are not persuasive. Applicant's arguments with respect to the Ciarrocca et al patent are persuasive and this ground of rejection has been withdrawn.

With regard to Abele et al, applicant contends that the Abele et al fail to disclose an "open tubular-shaped coil" as now recited in amended claim 12. The examiner disagrees. The coil electrodes (58,60) of Abele et al are certainly tubular in nature, as they extend along the tubular catheter body. Moreover, each end of the electrodes are "open" such that the needle electrode may pass through the lumen of the electrodes. While it is acknowledged that the Abele et al electrodes are not free-standing or unsupported as shown in applicant's Figure 16B, they are still deemed to read on a broadly interpreted "open tubular-shaped coil" since the ends of the coils are open, albeit with a catheter inserted therethrough.

Art Unit: 3739

Concerning the Edwards reference, applicant contends that the electrode is situated within coil electrode. It is noted that the claims do not specifically recite that the entirety of the active electrode is distal to the coil return electrode. In fact, each of claims 12 and 51 recite an active electrode that extends through the coil and is distal to the coil. As such, the Edwards active electrode (12) is deemed to be distal to the coil electrode since at least a portion of the electrode extends beyond the coil (14). Moreover, it is noted that Edwards disclose an insulation covering the active and return electrodes. Other Edwards patents (e.g. 5,370,675) teach that such an insulation covering is slidable to adjust the length of the electrodes. Such a teaching would be relevant should applicant amend the claims.

Applicant has not substantively argued the 35 USC 103 rejections, and has not addressed the Double patenting rejections. These rejections are maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 3739

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Primary Examiner

Art Unit 3739

mp May 17, 2006